Physician Order/Prescription & Statement of Medical Necessity

Please fax completed form to Chiesi Total Care℠ staff at 1-866-565-7794.

PATIENT INFORMATION

Patient Name (Last, First) _____

Social Security # _____ - _____ - _____ Sex: ☐ Male ☐ Female Date of Birth _____/_____/_____ (mm/dd/yyyy)

Address _____ City _____ State _____ ZIP _____

Primary Phone (Required) _____ Cell Phone _____ Language: ☐ English ☐ Other _____

INSURANCE INFORMATION

☐ No Insurance

Primary Prescription	**Primary Medical**	**Secondary Medical**
Insurance _____	**Insurance** _____	**Insurance** _____
Policy Holder _____	Policy Holder _____	Policy Holder _____
Policy ID # _____	Policy ID # _____	Policy ID # _____
Group # _____	Group # _____	Group # _____
Phone _____	Phone _____	Phone _____

Please attach copies of patient insurance and prescription cards—front and back.

MEDICAL INFORMATION

Diagnosis: ☐ Fabry (-Anderson) Disease ICD-10-CM E75.21

Height _____ inches or _____ cm Weight _____ lb or _____ kg Allergies: ☐ None ☑ Specify _____

Methods of Diagnosis (check all that apply):

☐ Enzyme Assay ☐ Genetic Testing ☐ Tissue Biopsy ☐ Other _____

Prior treatment and dose: _____ Last date of prior treatment and dose: _____

Please attach copies of medical history/physical summary, most recent alpha-galactosidase A (alpha-Gal A), genotype, plasma globotriaosylsphingosine (lyso-Gb3), current medications, and allergies.

ELFABRIO® (PEGUNIGALSIDASE ALFA-IWXJ) PRESCRIPTION/ORDER

Dosage — Elfabrio (pegunigalsidase alfa-iwxj)

☐ NDC 10122-160-02: **1 single-use 20-mg vial** ☐ NDC 10122-160-05: **5 single-use 20-mg vials** ☐ NDC 10122-160-10: **10 single-use 20-mg vials**

Actual Dose (mg*) _____ Frequency* _____ Number of Refills _____

*The recommended dosage is 1 mg/kg of body weight every 2 weeks, administered as an intravenous infusion.

Please list any additional treatment information, including follow-up evaluations: _____

_____

SITE OF SERVICE

Preferred Acquisitions Channel:

☐ Buy and Bill ☐ Specialty Pharmacy to Bill

Preferred Site of Infusion:

☐ Prescribing Physician's Site-of-Care Office (if this option is selected, please proceed to the next section)

☐ Alternate Site of Care ☐ Hospital Outpatient ☐ Other _____

Name of Institution/Practice Name _____ Physician or Infusion Provider Name _____

Provider's Specialty _____

Address _____ City _____ State _____ ZIP _____

Office Contact _____ Email _____

Office Phone (and Extension) _____ Office Fax _____ Site Tax ID _____

(Please continue on other side—signature required) — Please see Important Safety Information for Elfabrio, including Boxed Warning, on the back of this form and accompanying Full Prescribing Information.

PHYSICIAN/OFFICE INFORMATION

Prescriber's Name (Print) _____ Practice/Group Name _____

Address _____ Suite _____

City _____ State _____ ZIP _____

Office Contact Person _____

Office Phone _____ Office Fax _____

License # _____ NPI # _____

Preferred Medical Facility (Name, Phone) _____

List of Facilities Where Physician Has Privileges _____

By signing below, I certify that I am the prescribing provider mentioned above, that I am part of the Chiesi Total Care℠ Program, that the therapy described above is medically necessary, and that all the medical necessity information is true, accurate, and complete. The patient's records contain supporting documentation that substantiates the utilization and medical necessity of the products marked above. I provide permission to use my personal information and the personal information of the patient provided above to facilitate this request and complete any regulatory or legal requirements associated with this request. I understand that the personal information provided herein may be shared with Chiesi, successors, and their agents and service providers as needed to support this request. I also attest that I have obtained the patient's authorization to release the above information and such other personal information as may be necessary for the Chiesi Total Care Program and/or their agents and service providers. If the patient is 18 years old or younger, I attest that I have obtained permission from the patient's legal guardian. If my patient is eligible for free product, I understand that receiving free product is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid; nor may I bill any payer for administration of such product. I understand that any falsification, omission, or concealment of material fact may result in criminal liability.

X _____

Licensed Prescriber Signature (required – no stamps)

_____

Printed Name Date

ATTENTION: E-prescribe or use the official state prescription form where required by state law. No stamped signatures or signing on behalf of the prescriber.

Questions? Chiesi Total Care is here to help! Please contact Chiesi Total Care at 1-833-656-1056 if you have questions regarding this form.

Indication

Elfabrio® (pegunigalsidase alfa-iwxj) is indicated for the treatment of adults with confirmed Fabry disease.

Important Safety Information

WARNING: HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS

Patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available during Elfabrio administration. If a severe hypersensitivity reaction (eg, anaphylaxis) occurs, discontinue Elfabrio immediately and initiate appropriate medical treatment. In patients with severe hypersensitivity reaction, a desensitization procedure to Elfabrio may be considered.

Prior to Elfabrio administration, consider pretreating with antihistamines, antipyretics, and/or corticosteroids. Inform patients and caregivers of the signs and symptoms of hypersensitivity reactions and infusion-associated reactions (IARs), and instruct them to seek medical care immediately if such symptoms occur.

- If a severe hypersensitivity reaction (including anaphylaxis) or severe IAR occurs, immediately discontinue Elfabrio administration and initiate appropriate medical treatment.
- If a mild to moderate hypersensitivity reaction or IAR occurs, consider slowing the infusion rate or temporarily withholding the dose.

In clinical trials, 20 (14%) Elfabrio-treated patients experienced hypersensitivity reactions. Four Elfabrio-treated patients (3%) experienced anaphylaxis reactions that occurred within 5 to 40 minutes of the start of the initial infusion. The signs and symptoms of hypersensitivity reactions and anaphylaxis included headache, nausea, vomiting, throat tightness, facial and oral edema, truncal rash, tachycardia, hypotension, rigors, urticaria, intense pruritus, moderate upper airway obstructions, macroglossia, and mild lip edema.

In clinical trials, 41 (29%) Elfabrio-treated patients experienced one or more infusion-associated reactions, including hypersensitivity, nausea, chills, pruritus, rash, chest pain, dizziness, vomiting, asthenia, pain, sneezing, dyspnea, nasal congestion, throat irritation, abdominal pain, erythema, diarrhea, burning sensation, neuralgia, headache, paresthesia, tremor, agitation, increased body temperature, flushing, bradycardia, myalgia, hypertension, and hypotension.

A case of membranoproliferative glomerulonephritis with immune depositions in the kidney was reported during clinical trials. Monitor serum creatinine and urinary protein-to-creatinine ratio. If glomerulonephritis is suspected, discontinue treatment until a diagnostic evaluation can be conducted.

When switching to Elfabrio from a prior enzyme replacement therapy, the risk of hypersensitivity reactions and infusion-associated reactions may be increased in certain patients with pre-existing anti-drug antibodies (ADAs). Consider monitoring IgG and IgE ADAs and clinical or pharmacodynamic response (eg, plasma lyso-Gb3 levels).

The most common adverse reactions (≥15%) were infusion-associated reactions, nasopharyngitis, headache, diarrhea, fatigue, nausea, back pain, pain in extremity, and sinusitis.

Please see accompanying Full Prescribing Information for Elfabrio.

For more information, visit hcp.elfabrio.com.

PP-EF-0034 V2.0

ELFABRIO®
(pegunigalsidase alfa-iwxj)